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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,285	12/21/2001	Paul Sammak	00,1290-A	6817

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,285	Applicant(s) SAMMAK ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Information Disclosure Statement

The Information Disclosure Statements filed 1/30/02 and 3/11/03 have been considered in full.

Specification

The disclosure is objected to because of the following informalities: the phrase "priority to" in the first sentence on page 1 should be --benefit of--.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim construction is improper. The claims properly begin with "We claim:" but claim 1 also recites "The present invention provides..." which is improper claim language. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 appears to be directed to both a method and "software". See below. A computer program, per se, is not considered

statutory subject matter, as set forth in MPEP 2106.IV. Therefore the embodiment of the claim directed solely to "software" wherein there are no limitations that the "software"; i.e. program steps, be embodied in a computer-readable medium, on a computer, etc. is nonstatutory. Applicant should note that claims 2-20, clearly directed to a method, and claim 21, which recites a program embodied on a computer readable storage medium, are not rejected herein.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled for a method wherein a reference point is defined for each structure mask of individual cells in a field of view, then a cell identification is assigned to each reference point and used to correlate cells at different time points because neither the instant specification nor the prior art teach how to do so.

The prior art teaches generally how to create structure masks for objects in a field of view (see e.g. IDS ref: WO 98/38490, p. 31), and teaches that masks may be labeled. However, *assigning* a “blob label” to a mask, as taught by ‘490, does not appear to be the same as *defining* a reference of each structure mask, as recited in the instant claims 1 and 21. The prior art does not teach identifying cells by assigning a cell definition to a defined reference point. The guidance found in the specification on pages 5-6 defines a “reference point” as a single point defined *relative to a cell structure*. The specification further discloses, on page 6 that images may be acquired and “thresholded” to produce a structure mask. It appears from the disclosure of pages 5 and 6, however, that a reference point (i.e. relative to a structure) of a cell is identified or defined *prior to* production of a structure mask. The specification is silent with regard to defining a structure point *of a structure mask*. The specification discloses, in what appears to be working example on page 25, that nuclear zones of influence may be created and that cells may be segmented by defining *domains* within a cell. However, it is not clear what, if any of the steps on page 25 corresponds to “defining a structure point” of “each” structure mask. The specification does not teach how to assign a cell identification to an assigned reference point anywhere. The knowledge of skill in the art for imaging cells is acknowledged to be high, and there is a fair degree of certainty in

the art for using digitized images to track cell movements. See for example, McNally et al. (IDS ref: SPIE, (1994) vol. 2302, pp. 342-351) and VOLLMER et al. (J. Leuk. Biol. (1992) vol. 52, no. 6, pp. 630-636). Despite the high level of skill and degree of certainty in the art, however, and due to the lack of teaching in either the instant specification or prior art for how to define a reference point of a structure mask, and for how to assign a cell identification to such a defined reference point, it would require undue experimentation for one skilled in the art to practice the claimed method steps.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

A method and program wherein a reference point is defined for each structure mask of individual cells in a field of view, then a cell identification is assigned to each reference point and used to correlate cells at different time points, is not described by the instant specification. The specification provides literal support for the language of the claims on page 5, and defines a "reference point" on page 5-6 as a single point defined *relative to a cell structure*. The specification further discloses, on page 6 that images may be acquired and "thresholded" to produce a structure mask. It appears from the disclosure of pages 5 and 6, however, that a reference point (i.e. relative to a

structure) of a cell is identified or defined *prior to* production of a structure mask. The specification also discloses generation of a nuclear mask on page 25. Nowhere does the specification disclose defining a reference point of a structure mask. The specification does not disclose assigning a cell identification to individual (i.e. "each) reference points within a field of view. As the specification does not provide a clear, complete description of the claimed method/program steps, the claims are rejected for a lack of written description.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to "methods and software" for tracking individual cells, then recites what appear to be either program or method steps. As is it unclear whether applicant intends a method or a program (software), the claims are indefinite.

Claims 1 and 21 each recites a step (c) of creating a structure mask for cells in a field of view. It is generally known in the art that a structure mask may be created for cells/objects wherein chosen elements of an object are blocked or removed from an

image of the object. In order to create such a mask, however, one must know what to block or remove; i.e. the parameters for creating the mask must be known or selected. The instantly filed specification discloses, on page 6 that images may be acquired and “thresholded” to produce a structure mask, but does not disclose any particular threshold. The claims recite no limitations, parameters, etc. with regard to a threshold or other parameters used to create the claimed structure mask. As one skilled in the art would not know the metes and bounds intended by applicant for his structure mask, the claims are indefinite.

Claims 1 and 21 each recites a step (d) of defining a structure point of each structure mask. The specification is silent with regard to defining a structure point of a structure mask. The specification discloses on page 25 that nuclear zones of influence may be created and that cells may be segmented by defining domains. However, it is not clear what, if any of the steps on page 25 corresponds to “defining a structure point” of “each” structure mask. It is unclear what definition is to be applied to any individual structure mask, or whether the definition is to be applied to the mask as a whole, to individual areas within the structure mask, etc. Does applicant intend to define a reference point for each area within a structure mask, or for particular segments of cells? As the step, and definition, intended are unclear, the claim is indefinite.

Claims 1 and 21 each recites a step (f) of repeating various steps “at a second time point”. As no first time point is recited anywhere in the claims, recitation of a second time point is confusing, and the claims are indefinite. It is noted that claim steps (a)-(e) may occur over a time range and not necessarily at a single point in time,

therefore the examiner does not consider "a first time point" to be inherent for any particular step or series of steps.

Claims 1 and 21 recite the phrase "the first time point" in step (g). There is no antecedent basis for this phrase in the claims, therefore the claims are indefinite.

Claims 1 and 21 are directed to a method and program for tracking individual cells, but the steps merely identify particular cells. The claims do not recite any actual steps of tracking a cell; i.e. following movement of the cell over a series of time points. As it is unclear whether applicant intends a method for tracking individual cells, or actually intends a method for identifying particular cells in a field of view, the claims are indefinite.

Conclusion

Claims 1-21 are rejected; the specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
RECEIVED

Stephen A. Moran

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